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Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC.

One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).



NOPPER-JAUNKY, A Primary Examiner . for the Examining Division





Enclosure(s):

2 page/s reasons (Form 2906)

The examination is being carried out on the following application documents:

Description, Pages

1-40

as originally filed

Claims, Numbers

1-12

as originally filed

- 1. PCT application WO 2005/020950 (D1) published on 10.03.2005 claims the priority dates of 28.08.2003 and 03.09.2003. It has been supplied to the European Patent Office in one of its official languages according to Article 153(3) and (4) EPC and the filing fee provided for in Rule 159(1)(c) EPC or Article 39(1) PCT has been paid. The requirements of Rule 165 EPC are thus fulfilled. Its content as filed is therefore considered to be comprised in the state of the art relevant to the question of novelty, pursuant to Article 54(3) EPC. This earlier application discloses (see ex. 11-13) O/W emulsions comprising 1% by weight of sodium surfactin, 0.2% by weight of xanthan gum and different oil components (olive oil, jojoba oil, cetostearyl oil...). Thus, D1 is prejudicial to the novelty of the subject-matter of claims 1,4-8,10-12 of the present application.
- 2. The applicant is invited to file new claims which take account of the above comments.
 - In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines E-II, 1).

If the applicant considers it appropriate, these indications could be submitted in

handwritten form on a copy of the relevant parts of the application as filed.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

STREHL SCHÜBEL-HOPF & PARTNER PATENTANWÄLTE EUROPEAN PATENT ATTORNEYS

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June 16, 2008

EPO - Munich 23 1**1 6. Juni 2008**

05 721 568.3-2108 Showa Denko K.K. Our File EPA-64082

This is in response to the official communication dated February 27, 2008.

We herewith file

- an amended set of claims 1 to 11 and
- amended pages 1, 3 to 5, and 8 of the description.

Amended claim 1 is based on original claims 1 and 2. The other claims were renumbered.

The description was brought into conformity with the amended claims.

Original claim 2 was not objected to by the Examiner. Therefore, amended claim 1 is novel over the disclosure of D1.

Since D1 is prior art only pursuant to Art. 54(3) EPC and no other document was cited as relevant prior art by the Examiner, the inventive step of the subject-matter of the present application should be acknowledged.

Dr. Heinrich Fischer Association No. 94

Enclosures

DESCRIPTION

FOR SKIN AND COSMETICS USING THE COMPOSITION

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CROSS-REFERENCE TO THE RELATED APPLICATIONS

This is an application filed pursuant to 35 U.S.C. Section 111 (a) with claiming the benefit of U.S. Provisional application Serial No. 60/558,548 filed April 2, 2004, under the provision of 35 U.S.C. Section 111 (b), pursuant to 35 U.S.C. Section 119 (e) (1).

TECHNICAL FIELD

The present invention relates to an oil-in-water emulsified composition. Specifically, the present invention relates to an oil-in-water emulsified composition comprising lipopeptide compounds derived from microorganisms and xanthan gum, which is excellent in feeling upon use, moisture retention, emollient property and stability as well as environmental suitability and safety for living organisms.

BACKGROUND ART

Oil-in-water emulsified compositions, providing fresh feelinguponuse, are being widely used in cosmetics, quasi-drugs and the like.

Generally, emulsified products are unstable to heat, and various methods for stably retaining the emulsified state are known. Among them, a method of increasing viscosity of the external phase is often employed. In case of oil-in-water emulsified composition, natural water-soluble polymers such as xanthan gum, locust bean gum, guar gum and carrageenan, and

DISCLOSURE OF THE INVENTION

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An object of the present invention lies in provision of an oil-in-water emulsified composition which is excellent in feeling upon use, moisture retention, emollient property and stability as well as environmental suitability and safety for living organisms.

Another object of the present invention lies in provision of external preparations for skin and cosmetics using the oil-in-water emulsified composition.

As a result of intensive investigations to solve this problem, the present inventors have found that by using lipopeptide compounds derived from microorganisms and xanthan gum in combination, even without using synthetic water soluble polymer or nonionic surfactant, good emulsification can be attained to thereby obtain an oil-in-water emulsified composition which is excellent in feeling upon use, moisture retention, emollient property and stability as well as environmental suitability and safety for living organisms, and thus completed the present invention.

Accordingly, the invention relates to the following items.

- 1. An oil-in-water emulsified composition, which comprises 0.1 to 5 % by mass of (A) lipopeptide compound derived from a microorganism, 0.05 to 1.5 % by mass of (B) xanthan gum,
- 25 (C) oil component and (D) water,
 - 2. The oil in water emulsified composition according to the above item 1, wherein the content of the oil component is from 25 to 70 % by mass.
- 2.8 The oil-in-water emulsified composition according to the above item 1, wherein the water content is from 15 to 55 % by mass.

. 3. A The oil-in-water emulsified composition according to the above item 1, wherein the microorganism-derived lipopeptide compound (A) is at least one species selected from surfactins, its analogous compounds and salts thereof.

The oil-in-water emulsified composition according to the above item #, wherein the surfactin or its analogous compound comprises at least one or more compounds as represented by the formula (1) below:

(in the formula, X represents an amino acid residue selected from the group consisting of leucine, isoleucine, valine, glycine, serine, alanine, threonine, asparagine, glutamine, aspartic acid, glutamic acid, lysine, arginine, cysteine, methionine, phenylalanine, tyrosine, tryptophan, histidine, proline, 4-hydroxyproline and homoserine, and R represents a normal alkyl group having from 8 to 14 carbon atoms, an isoalkyl group having from 8 to 14 carbon atoms or an anteisoalkyl group having from 8 to 14 carbon atoms).

5 % The oil-in-water emulsified composition according to the above item \$\mathbf{4}\$, wherein X is residue of leucine, isoleucine or valine.

6.% The oil-in-water emulsified composition according to the above item #, wherein the salt is at least one compound selected from the group consisting of sodium salt, potassium salt,

25 monoethanolamine salt, diethanolamine salt, triethanolamine salt, arginine salt and lysine salt.

7.% The oil-in-water emulsified composition according to the above item 2, wherein the microorganism-derived lipopeptide compound (A) is sodium surfactin.

- 8. 9. The oil-in-water emulsified composition according to any one of the above items 1 to 8, comprising no nonionic surfactant.
- 9 10. The oil-in-water emulsified composition according to any one of the above items 1 to 8, comprising no acrylic acid-based water-soluble polymer.
- 10. N. An external preparation for skin comprising the

 10 oil-in-water emulsified composition according to any one of
 the above items 1 to 10.
 - 11.12. A cosmetic comprising the oil-in-water emulsified grouposition according to any one of the above items 1 to 10.
 The invention is explained below in detail.
- Examples of the lipopeptide compound (A) used in the invention include lipopeptide compounds produced by microorganisms of genus *Bacillus* such as *Bacillus* subtilis described in JP-A-2000-327591 (WO99/62482). Preferable examples include salts of surfactin and salts of analogous compounds thereof.

The surfactin herein refers to a compound represented by the formula (1):

RCHCH₂CO-_L-Glu-_L-Leu-_D-Leu-_L-Val-_L-Asp-_D-Leu-_L-X
$$(1)$$

or a composition containing two or more kinds of the compounds represented by the formula (1).

In the above formula (1), X represents an amino acid residue selected from the group consisting of leucine, isoleucine,

particularly limited and any kind can be used as long as the xanthan gum is generally used as raw material for external Preferable examples of the xanthan gum preparation for skin. usable in the present invention include Echo Gum, Echo Gum T and Echo Gum BT distributed by DAINIPPON PHARMACEUTICAL CO., LTD. The compounding amount of the xanthan gum in the composition of the present invention is preferably 0.05 to 1.5 % by mass, more preferably 0.08 to 0.7 % by mass, still more preferably 0.1 to 0.4 % by mass. If the amount of the xanthan gum is less than 0.05 % by mass, sufficient stability of the emulsified composition cannot be obtained. The amount of the xanthan gum exceeding 1.5 % by mass is unpreferable, since it would deteriorate feeling upon using the composition of the present invention.

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The oil-in-water emulsified composition of the present invention contains oil component (C). Any oil material can be employed unless it is arbitrarily mixed with water. It is preferable that one or more selected from hydrocarbons, natural fats and oils, fatty acids, higher alcohols, alkyl glyceryl ethers, esters and silicone oils be compounded in. The total compounding amount of oil components is preferably 25 to 70 % by mass, more preferably 30 to 60 % by mass, based on the total amount of the composition.

The oil-in-water emulsified composition of the present invention contains water (D). The water content is to be contained as balance, and a preferable range of the water content is from 15 to 55 % by mass, and particularly preferred is from 20 to 50 % by mass.

The oil-in-water emulsified composition of the present invention does not necessarily require use of nonionic surfactants or acrylic acid-base water-soluble polymers which

CLAIMS

1. An oil-in-water emulsified composition, which comprises 0.1 to 5 % by mass of (A) lipopeptide compound derived from a microorganism, 0.05 to 1.5 % by mass of (B) xanthan gum, (C) oil component and (D) water,

2. The oil-in-water emulsified composition according to claim 1, wherein the content of the oil component is from 25 to 70 % by mass.

- 2.% The oil-in-water emulsified composition according to claim 1, wherein the water content is from 15 to 55 % by mass.
- 3.4. The oil-in-water emulsified composition according to claim 1, wherein the microorganism-derived lipopeptide compound (A) is at least one species selected from surfactins, its analogous compounds and salts thereof.
- The oil-in-water emulsified composition according to claim 4, wherein the surfactin or its analogous compound comprises at least one or more compounds as represented by the formula (1) below:

wherein X represents an amino acid residue selected from the group consisting of leucine, isoleucine, valine, glycine,

serine, alanine, threonine, asparagine, glutamine, aspartic acid, glutamic acid, lysine, arginine, cysteine, methionine, phenylalanine, tyrosine, tryptophan, histidine, proline, 4-hydroxyproline and homoserine, and R represents a normal alkyl group having from 8 to 14 carbon atoms, an isoalkyl group having from 8 to 14 carbon atoms or an anteisoalkyl group having from 8 to 14 carbon atoms.

- 5. 6. The oil-in-water emulsified composition according to claim \$\mathbf{S}\$, wherein X is residue of leucine, isoleucine or valine.
- The oil-in-water emulsified composition according to claim #, wherein the salt is at least one compound selected from the group consisting of sodium salt, potassium salt, monoethanolamine salt, diethanolamine salt, triethanolamine salt, arginine salt and lysine salt.
- 7. 8. The oil-in-water emulsified composition according to claim A, wherein the microorganism-derived lipopeptide compound (A) is sodium surfactin.
- 8. S. The oil-in-water emulsified composition according to any one of claims 1 to 8, comprising no nonionic surfactant.
- 9.10. The oil-in-water emulsified composition according to any one of claims 1 to 8, comprising no acrylic acid-based water-soluble polymer.
- 10 11. An external preparation for skin comprising the oil-in-water emulsified composition according to any one of claims 1 to 10.

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12. A cosmetic comprising the oil-in-water emulsified composition according to any one of claims 1 to 10.